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10/587,934	02/22/2007	Toshihiko Miyamoto	2006_1252A	5698
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EXAMINER				
HENKEL, DANIELLE B				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/587,934

Applicant(s)

MIYAMOTO ET AL.

Examiner

DANIELLE HENKEL

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This is the initial Office action on the 10/587934 application filed on November 26, 2008.
2. Claims 1-5 and 7-10 remain pending and have been fully considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MIYAMOTO (US 6197574), in view of NASON (US 5266266), and further in view of MATKOVICH (US 4731061).

a. With respect to claim 1, MIYAMOTO teaches a bacterium detector comprising a hollow cylindrical container with an opening and a cover (cap) that can be freely inserted (engaging) into (forms closed system) and detached from the opening (Column 20, lines 47-49). The disclosed container is used for incubation (space for culturing) (Column 21, lines 46-48). The disclosed cap allows for the maintenance of a tight-sealed system (hermetically sealed) (Column 25, line 30) and includes a microorganism collecting member (sample collecting member) extending vertically to the opening of the container (capable of being inserted and drawn from) (Column 21, lines 12-15). MIYAMOTO teaches the cap contains (cap is hollow) a bag-shaped member or vessel (storage space) enclosing (not in contact with collector) medium for the incubation of specific microorganisms (Column 20, lines 51-53). The medium storage space is released into the container when a strong compressing force outside the cover breaks the vessel resulting in the microorganism collecting part being dipped into the medium (Column 22, lines 13-20). MIYAMOTO also teaches the upper end of the cap has a second bag shaped vessel which encloses a disinfectant (Column

20, lines 54-57). The second storage space is also broken by applying a sufficient force from outside the cover causing the release of disinfectant into the container causing the mixture of the microorganisms to be mixed with the disinfectant (Column 23, lines 4-13). MIYAMOTO also discloses the cover may be constituted from soft plastics such as soft resin (synthetic resin) and is connected to the container by a screw thread or bayonet (engaging portion) (Column 23, lines 49-55). The cap includes a partition member with holes (capable of communicating with container) (Column 20, lines 63-64). MIYAMOTO teaches the cap has a partition member between the first and second liquid enclosing bag members (independent chambers) and a partition between the first bag member and the opening of the cap (Column 20, line 61- Column 21, line 2). MIYAMOTO teaches the independent chambers housing the fluid ampules are formed of the partition members at the lower side and a wall portion of the cap body (Figure 1). MIYAMOTO also discloses the first and second bag members are opened by applying a strong compressing force to the outside of the cap allowing the liquid to be released through holes in both partition members (first and second opening forming part) in the partition members (Column 22, lines 13-20). MIYAMOTO does not disclose the opening-forming part of the partition member comprising a stick like protrusion. However, NASON teaches a specimen test unit with a break-off nib (protrusion) at the rear end of the specimen collecting swab (axial direction) where the swab and break off nib (opening forming part) are connected at a reduced diameter score (thin walled

fragile part) with a central bore (opening) located within (Column 4, lines 35-42, Figure 3). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the bacterium detector of MIYAMOTO to include the break off nib opening forming part of NASON. The motivation would have been NASON teaches the disclosed device allows for reagent delivery without the use of expensive and dangerous glass ampoules or difficult and unreliable rupturable plastic compartments (Column 1, line 62-Column 2, line 19). Neither MIYAMOTO nor NASON explicitly disclose the first wall of the cap body and the stick like protrusion having a cross sectional shape wherein the vertical and horizontal lengths are unequal. However, MATKOVICH teaches a plastic closure and applicator cap in which the tip portion of the cap body has an extremity (wall) that is preferably flat (cross section vertical and horizontal lengths unequal) (Column 4, lines 57-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the cap member of the bacterium detector of MIYAMOTO with the break off tip of NASON with the flat shape of MATKOVICH. The motivation would have been that MATKOVICH discloses the flattened shape is easily manually broken in the intended manner without special tools required (Column 2, lines 40-45). In the cap disclosed by MATKOVICH the cap and the break off tip are the same device, however, in combining the flattened shape of MATKOVICH with the break off tip device combination of MIYAMOTO and NASON it would be an obvious substitution to make both the cap and the break off tip with a flattened shape.

- b. With respect to claim 2, MIYAMOTO does not disclose the opening-forming part of the partition member comprising a stick like protrusion. However, NASON teaches a specimen test unit with a break-off nib (protrusion) at the rear end of the specimen collecting swab (axial direction) where the swab and break off nib (opening forming part) are connected at a reduced diameter score (thin walled fragile part) with a central bore (opening) located within (Column 4, lines 35-42, Figure 3). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the bacterium detector of MIYAMOTO to include the break off nib opening forming part of NASON. The motivation would have been NASON teaches the disclosed device allows for reagent delivery without the use of expensive and dangerous glass ampoules or difficult and unreliable rupturable plastic compartments (Column 1, line 62-Column 2, line 19).
- c. With respect to claim 3, MIYAMOTO teaches the cap is hollow and made of synthetic resin as addressed above. NASON teaches the use of a resiliently deformable plastic material as the housing (wall) when manually bent (external force) is effective to bend the rod portion of the nib (abutting the wall against the protrusion) relative to the shaft (in perpendicular axis) of the swab. Breaking off the nip creates an opening in the reduced diameter portion of the housing (Column 5, lines 48-60).
- d. With respect to claim 4, MIYAMOTO teaches the first liquid is medium for the incubation of specific microorganisms and the second liquid is a disinfectant (Column 20, lines 51-57).

- e. With respect to claim 5, NASON teaches the nib is an integral portion of a seal (partition) in the cap (hollow container side) that allows for the rear end of the swab to be seated (movably fitted) therein (concave) (Column 2, lines 61-65). This break off nib of NASON occurs between the swab shaft and break off nib as the device of NASON includes only one reagent chamber. However in the combination of NASON with the two chamber detector of MIYAMOTO it would be an obvious substitution to use the break off nib with the concave for the swab shaft of NASON at the second partition as well.
- f. With respect to claim 7, neither MIYAMOTO nor NASON explicitly disclose the first wall of the cap body and the stick like protrusion having a cross sectional shape wherein the vertical and horizontal lengths are unequal. However, MATKOVICH teaches a plastic closure and applicator cap in which the tip portion of the cap body has an extremity (wall) that is preferably flat (cross section vertical and horizontal lengths unequal) (Column 4, lines 57-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the cap member of the bacterium detector of MIYAMOTO with the break off tip of NASON with the flat shape of MATKOVICH. The motivation would have been that MATKOVICH discloses the flattened shape is easily manually broken in the intended manner without special tools required (Column 2, lines 40-45). NASON In the cap disclosed by MATKOVICH the cap and the break off tip are the same device, however, in combining the flattened shape of MATKOVICH with the break off tip device combination of MIYAMOTO and NASON it would be an

obvious substitution to make both the cap and the break off tip with a flattened shape.

g. With respect to claim 8, NASON teaches the break off nib (stick like protrusion) has an upper rod segment (cross section with vertical length approximately equal to horizontal) formed as a continuation of the swab shaft (Column 4, lines 35-40, Figure 4).

h. With respect to claim 9, NASON discloses the cap body from the closed end to the seal collar (second wall portion) has a cylindrical geometry (cross section vertical length approximately equal to horizontal) (Column 4, lines 58-60).

i. With respect to claim 10, MIYAMOTO teaches a cap member is located on the top end (second wall portion) of the cover member (cap body) (Column 35, lines 47-52) that can be slid to the side of the container (movable) (Column 36, line 36-37). MIYAMOTO does not explicitly disclose this cap is a protecting sheath, however, NASON discloses the use of an over cap that closes an outlet (protecting sheath) (Column 8, lines 15-18). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the cap member of the bacterium detector of MIYAMOTO to include the protecting overcap of NASON. The motivation would have been NASON discloses the overcap prevents the flow of liquid through a tip (opening of break off nib) until it is removed (Column 8, lines 30-33).

Response to Arguments

7. Applicant's arguments filed 11/26/2008 have been fully considered but they are not persuasive for the reasons listed below.
8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "wherein neither a culture-medium –filled ampule or disinfectant –filled ampule are necessary", Page 7) are not recited in the rejected claim(s). The ampules taught by MIYAMOTO meet the claim language of a "structure serving as a storage space for storing a culture medium" and "structure serving as a storage space for storing a disinfectant". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
9. In response to applicant's argument that MIYAMOTO fails to teach first or second opening forming means in the partition members and independent chambers formed of the partition members, further explanation of the structures of MIYAMOTO that meet this claim language are included in the rejection of claim 1 above.
10. In response to applicant's argument that NASON and MATKOVICH are not related to a technique for handling toxic food-poisoning bacteria, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

11. In response to applicant's argument that the references NASON and MATKOVICH fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a device enclosing two kinds of liquids in one container", and "a technique for supplying each of two liquids into a room of one container successively and securely" Page 8) are not recited in the rejected claim(s). The references of NASON and MATKOVICH in combination with MIYAMOTO meet the language of the claims as shown in the above rejection. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
12. In response to applicant's arguments against the references individually, specifically NASON and MATKOVICH, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
13. In response to applicant's argument that there is no suggestion to combine the references of MATKOVICH with the combined MIYAMOTO and NASON, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, NASON teaches a bacteria device as

taught by MIYAMOTO including a break-off nib at the rear end of the specimen collecting swab (axial direction) where the swab and break off nib (opening forming part) are connected at a reduced diameter score (thin walled fragile part) with a central bore (opening) located within (Column 4, lines 35-42, Figure 3) to allow for reagent delivery without the use of expensive and dangerous glass ampoules or difficult and unreliable rupturable plastic compartments (Column 1, line 62-Column 2, line 19). MATKOVICH also teaches using a break-off nib to allow for fluid delivery and further specifies the desired design to be a flattened shape because it is easily manually broken in the intended manner without special tools required (Column 2, lines 40-45). Therefore one of ordinary skill in the art would look to the teachings of NASON and MATKOVICH as analogous art in the area of break-off nibs allowing for fluid delivery.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/DANIELLE HENKEL/
Examiner, Art Unit 1797